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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/823,980	03/25/1997	AMY J. WEINER	CHIR-0108	8052

7590 06/29/2005

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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/823,980

Applicant(s)

WEINER ET AL.

Examiner

Ron Schwadron, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-44, 52, 55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 41-44, 52, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/20/2005 has been entered.
2. Claims 41-44, 52, 55, 56 are under consideration.
3. The previously pending rejection of claims 41-44, 52, 55, 56 and 53 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 47, 51, 54 of copending Application No. 08/437952 is withdrawn in view of the TD filed 1/21/2005.
4. The previously pending rejection of claims 41-44, 52, 55, 56 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43, 44, 47, 48, 50, 51 of copending Application No. 08/438183 is withdrawn in view of the TD filed 8/23/2004 and the cancellation of claim 53.
5. The rejection of claims 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.
6. References not considered on the enclosed PTO 1449 were already of record in a previously filed PTO-1449 or 892.
7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 41-44,52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8,24,33,38 of U.S. Patent No. 6,630,298. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, a fusion peptide containing a peptide encompassing the peptide recited in the claims is found in the peptide of Figure 7A-7F (SEQ. ID. No. 5, amino acids 113-143) which is recited in claims 8,24,33,38. The peptide recited in claims 8,24,33,38 contains additional nonHCV amino acids (SOD at amino terminus as per depicted in Figure 6 which discloses the peptide of Figure 7A-7F). The agents recited in claims 43/44 are art known linking agents that could be used to link the fusion protein to a support. The fusion protein recited in claims 8,24,33,38 would have been supplied with PBS (the composition of claim 52).

9. Claims 41-44,52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8,11-21 of U.S. Patent No.6,632,601. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, a fusion peptide containing a peptide encompassing the peptide recited in the claims is found in the fusion protein of Figure 5A-5F (SEQ. ID. No. 4, amino acids 200-230). The peptide recited in the claims contains additional

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nonHCV amino acids (SOD at amino terminus as per depicted in Figure 4 which discloses the peptide of Figure 5A-5F). The agents recited in claims 43/44 are art known linking agents that could be used to link the fusion protein to a support. The fusion protein recited in claims 5-8,11-21 could have been supplied with PBS (the composition of claim 52).

10. Claims 41-44,52,55,56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No.6,797,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, a fusion peptide containing a peptide encompassing the peptide recited in the claims is found in the fusion protein of Figure 5A-5F (SEQ. ID. No. 4, amino acids 200-230). The peptide recited in the claims contains additional nonHCV amino acids (SOD at amino terminus as per depicted in Figure 4 which discloses the peptide of Figure 5A-5F). Diphtheria toxin is an art known carrier protein which could have been added to the conjugate for purposes of increasing the immunogenicity for immunization purposes. The agents recited in claims 43/44 are art known linking agents that could be used to link the fusion protein to a support. The fusion protein recited in claims 1-4 could have been supplied with PBS (the composition of claim 52).

11. Claims 41-44,52,55,56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8,12,31,44-58 of copending Application No. 10/643853. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, a fusion peptide containing a peptide encompassing the peptide recited in the claims is found in the fusion protein of Figure 7A-7F (SEQ. ID. No. 5, amino acids 113-143). The peptide recited in claims 8,12,31,44-58 contains additional nonHCV amino acids (SOD at amino terminus as per depicted in Figure 6 which discloses the peptide of Figure 7A-

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7F). Diphtheria toxin is an art known carrier protein which could have been added to the conjugate for purposes of increasing the immunogenicity for immunization purposes. The agents recited in claims 43/44 are art known linking agents that could be used to link the fusion protein to a support. The fusion protein recited in claims ~~8,24,33,38~~ could have been supplied with PBS (the composition of claim 52). ~~8,12,31,44-58~~

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 41-44,52,55,56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-14,16,17,19,20,22-47 of copending Application No. 10/899715. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, a fusion peptide containing a peptide encompassing the peptide recited in the claims is found in the fusion protein of Figure 5A-5F (SEQ. ID. No. 4, amino acids 200-230). The peptide recited in the claims contains additional nonHCV amino acids (SOD at amino terminus as per depicted in Figure 4 which discloses the peptide of Figure 5A-5F). Diphtheria toxin is an art known carrier protein which could have been added to the conjugate for purposes of increasing the immunogenicity for immunization purposes. The fusion protein recited in claims ~~8,24,33,38~~ could have been supplied with PBS (the composition of claim 52). ~~6-14,16,17,19,20,22-47~~

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 41-44,52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15,16,31,32 of copending Application No. 10/658782. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, a fusion peptide containing a peptide encompassing the peptide recited in the claims is found in the fusion protein of SEQ. ID. No. 4, amino acids 113-143 or SEQ. ID. No. 6, amino acids 200-230. The peptides

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15, 16, 31, 32
recited in said claims ~~8, 24, 33, 38~~ contains additional nonHCV amino acids (SOD at amino terminus). The agents recited in claims 43/44 are art known linking agents that could be used to link the fusion protein to a support. The fusion protein recited in claims 8, 24, 33, 38 could have been supplied with PBS (the composition of claim 52).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday through Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644


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PRIMARY EXAMINER
GROUP 1800-1652